

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC and
LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE INC.,

Defendant.

C.A. No. 23-0377-JLH

ANDA CASE

FILED UNDER SEAL

**INGENUS PHARMACEUTICALS, LLC and LEIUTIS PHARMACEUTICALS LLP'S
ANSWERING LETTER BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO
STRIKE (D.I. 64)**

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Dated: January 3, 2025

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Dear Judge Hall:

Pursuant to the Court's Order (D.I. 61), Plaintiffs Ingenus Pharmaceuticals, LLC and Leiutis Pharmaceuticals, LLP ("Plaintiffs") respectfully oppose defendant Accord Healthcare, Inc.'s ("Defendant") motion to strike portions of Mr. Stephen Holzen's rebuttal expert report (D.I. 64).

Mr. Holzen has opined on long-felt need and copying, relying on Plaintiffs' sales, market share, and licensing. Courts routinely consider such commercial activity as supportive of long-felt need. Defendant's drastic exclusion request is unwarranted where (1) it was aware of Plaintiffs' sales and market share long before this lawsuit, and (2) it refused to take deposition testimony on *any* objective indicia of nonobviousness, and further declined to depose anyone except the '952 Patent inventors. Even after Defendant became aware of the June 2024 licensing of the '952 Patent to third party Dr. Reddy's Labs ("DRL") and Plaintiffs' intent to rely on the opinions of Mr. Holzen in September, 2024, Defendant refused to even consider seeking any additional discovery.

Factual Background. When considering whether to file its Abbreviated New Drug Application on Plaintiffs' patented cyclophosphamide drug product, Defendant relied heavily on Plaintiffs' sales and market share data. [REDACTED]

[REDACTED]

[REDACTED]

At the outset of this case, Plaintiffs notified Defendant in their Rule 26(a)(1) Disclosures that Ingenus' CEO, Dr. Samir Mehta, was a likely witness knowledgeable about "sales and marketing of Ingenus cyclophosphamide injection products." (Ex. 3, at 3). Defendant never deposed Dr. Mehta, and never issued a Fed. R. Civ. P. 30(b)(6) notice directed to commercial activity or any other topics. In fact, Defendant only deposed the '952 Patent inventors Kocherlakota Chandrashekhar and Banda Nagaraju. One week after Defendant served its Amended Invalidity Contentions on June 6, 2024, Plaintiffs supplemented their response to Defendant's Interrogatory No. 6, stating "Plaintiffs expect to rely on at least copying and long-felt need" as objective indicia of nonobviousness. (D.I. 64, Ex. B, at 5).¹ Plaintiffs identified the sales of its cyclophosphamide injection products as relevant to long-felt need, stating that "Plaintiffs' FDA approval and *commercial introduction of RTU formulations* of cyclophosphamide in July-August advantageously reduced preparation time, decreased drug volume per dose, and reduced waste as a multidose vial." (*Id.*, at 6). Defendant declined to ask Plaintiffs' witnesses any questions on copying, long-felt need, or Plaintiffs' commercial introduction of their cyclophosphamide drug product.

On June 11, 2024, Ingenus entered into a licensing agreement with DRL concerning the '952 Patent. Plaintiffs timely produced this license to Defendant on June 24, 2024, prior to the close of fact discovery. Defendant never sought any discovery regarding this (or any other) license from

¹ Defendant first requested supplementation to its first set of interrogatories on May 30, 2024, and again on June 12, 2024. (Ex. 4, at 2). Plaintiffs responded to these repeated requests on June 12, 2024, confirming that they would serve their supplementations the next day, which they did. (Ex. 4, at 1).

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Plaintiffs or DRL. On September 16, 2024, Plaintiffs disclosed Mr. Holzen to Defendant under the Protective Order (Ex. 5, at 1.), and subsequently produced two additional documents on Plaintiffs' sales covering up to July 2024 in September and October, 2024. (Ex. 6, at 1). Accord never complained or inquired about these productions. Instead, Defendant revealed its intent to preemptively strike Mr. Holzen's report after he was disclosed to Defendant (Ex. 6, at 1), a posture it maintained throughout the meet and confer that preceded this briefing. (Ex. 7, at 1).

Plaintiffs timely served Mr. Holzen's rebuttal report on December 9, 2024. (D.I. 64, Ex. A). In his report, Mr. Holzen opined that the '952 Patent addressed a long-felt but unmet need. (*Id.*, ¶33). He discussed factors relevant to long-felt need, including "a patented product's sales and market share, and evidence of licensing and copying when other non-patented alternatives existed in the market." (*Id.*, ¶¶34-61). Mr. Holzen explained that "Ingenus' NDA Product met a long-felt, unmet need in the market because it quickly achieved and retained significant sales and market share in the market for cyclophosphamide products, and Ingenus licensed the '952 Patent to those who used the claimed liquid formulations therein, despite the availability of non-liquid cyclophosphamide products in the market that could have been used instead. (*Id.*, ¶12).

Argument. Mr. Holzen's report should not be excluded, because it discloses additional proof supporting the already-disclosed contentions of long-felt need and copying. As a preliminary matter, before a Court considers whether the Third Circuit's *Pennypack* factors justify the "extreme" sanction of exclusion (requiring a showing of willful deception or "flagrant disregard" of a Court order), the Court must first determine whether there has been a failure to provide relevant information. *See Vectura Ltd. v. GlaxoSmithKline LLC*, 2019 U.S. Dist. LEXIS 55415, *3 (D. Del. Apr. 1, 2019) (citing *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997)). Here, there has been no failure to disclose. Other courts have found it to be dispositive "whether the allegedly undisclosed 'theory' is in fact a new theory or new element that was not previously identified [] or whether the 'theory' is instead the identification of additional evidentiary proof supporting those already disclosed contentions." *Bombardier Rec. Prods. v. Arctic Cat, Inc.*, 2016 U.S. Dist. LEXIS 184531, *24 (D. Minn. Apr. 19, 2016) (citing *Genentech, Inc. v. Trustees of University of Pennsylvania*, 2012 WL 424985, at *2 (N.D. Cal. Feb. 9, 2012) and *Oracle Am., Inc. v. Google Inc.*, 2011 WL 4479305, at *3 (N.D. Cal. Sept. 26, 2011)). Here, Mr. Holzen's report is the latter.

Both District Courts and the Federal Circuit routinely consider commercial activities, including sales and market share as evidence of long-felt but unmet need, just as Mr. Holzen has done in his report. *See Halozyme, Inc. v. Iancu*, 320 F. Supp. 3d 788, 809 (E.D. Va. Jul. 31, 2018) (finding lack of "commercial[] availability" dispositive of failing to meet "long-felt need"); *Spigen Korea Co. v. Ispeaker Ltd.*, 2018 U.S. Dist. LEXIS 225490, at *46-47 (C.D. Cal. Jul. 16, 2018) (considering sales as relevant to meeting a "long felt but unsolved need[]"); *Hildebrand v. Steck Mfg. Co.*, 395 F. Supp. 2d 1036, 1036 (D. Colo. Oct. 5, 2005) (analyzing commercial success and long-felt need together); *see also Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (considering commercial success in the context of long-felt need, but finding that the evidence didn't support the factor because there was no nexus with the patent claim at issue); *Marine Travelift, Inc. v. ASCOM SpA*, 2014 U.S. Dist. LEXIS 118202, at *19-24 (E.D. Wis. Aug. 25, 2014) (same); *Lewart Co. v. Acco Int'l, Inc.*, 428 F. Supp. 258, 264, 1976 (N.D. Ill. Apr. 30, 1976) (same).

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Likewise, courts routinely consider licensing as evidence of copying and satisfying a unmet long-felt need. *In re Tiffin*, 443 F.2d 394 (C.C.P.A. 1971) (affidavit sworn by a licensee in support of long-felt need added to the weight accorded to the affidavit); *B&H Mfg. v. Foster-Forbes Glass Co.*, 1993 U.S. Dist. LEXIS 21432, *17-18 (N.D. Ind. Jan. 6, 1993) (citing *Gillette Co. v. S.C. Johnson & Sons*, 919 F.2d 720, 725 (Fed. Cir. 1990)) (“the licensing agreements are objective evidence that the patents were non-obvious by showing commercial success, long-felt need, and copying by others.”).²

Even if the Court were to conclude that Mr. Holzen’s opinions on commercial sales, market share and licensing were based on objective indicia not previously disclosed by Plaintiffs, each of the *Pennypack* factors weigh against the extreme sanction of exclusion.

First, Defendant has not been prejudiced where it knew more than a month before the close of fact discovery that Plaintiffs intended to rely on commercial activity in support of “long-felt need” and “copying” (D.I. 64, Ex. B, at 5), but it refused to seek any discovery thereon, even after production of the DRL license. Notwithstanding, Defendant’s expert Jason McConville, Ph.D. was free to (and did) submit a reply report responding to Mr. Holzen’s opinions on sales, market share, and licensing. Defendant has not requested to depose Mr. Holzen, but is free to do so before the close of expert discovery on January 17, 2025. Defendant claims it would need discovery from Athenex and DRL, but Plaintiffs have produced hundreds of documents relating to Athenex, and it seems likely Defendant ignored them, just as it has ignored the opportunity to seek discovery regarding DRL. That Defendant did not take discovery related to “sales, market share, or licensing” “[b]ased on Ingenus’ representations that it was relying only on copying and long-felt but unmet need” (D.I. 64, at 2) is disingenuous since Defendant did not take discovery on any objective indicia, and ignores that Defendant could have sought discovery on commercial activity at any point in this case. Tellingly, Defendant threatened to strike Mr. Holzen’s report shortly after he was disclosed to them, and months before Mr. Holzen even provided a report. Defendant waited over 3 months to request the Court’s assistance and it made no effort to resolve the issue with Plaintiffs. (Ex. 7, at 1).

Defendant alleges bad faith, but offers nothing but attorney argument in support. To be sure, Defendant does not challenge Plaintiffs’ document production, and never requested any additional documents. Finally Mr. Holzen’s opinions go to the very heart of the case — whether the ’952 Patent is invalid for obviousness. The importance of this information weighs against exclusion.

Conclusion. For the foregoing reasons, Defendant’s request to strike certain portions of Mr. Holzen’s report should be denied.

² Defendant cites no authority to the contrary. *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013) cited by Defendant (D.I. 64 at 2) does not stand for the proposition that objective indicia are all distinct and non-overlapping. Rather, the case simply illustrates an exemplary obviousness analysis using objective indicia.

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Respectfully submitted,

/s/ Daniel A. Taylor

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cc: All Counsel of Record (via email)